DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region m3070n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973) 526-6009

October 18, 1999

WARNING LETTER

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

Patrick Deschenes
Chief Executive Officer
Community Blood Council of New Jersey, Inc.
1410 Parkside Avenue
Trenton, New Jersey 08638

File No.: 00-NWJ-06

Dear Mr. Deschenes:

During an inspection of Community Blood Council of New Jersey, Inc., located at 1410 Parkside Avenue, Trenton, New Jersey, from August 31-September 23, 1999, an Investigator from this office documented violations of Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Parts 600-680, as they relate to the collecting, processing and testing of blood and blood components. These deviations were cited on an FDA483 List of Inspectional Observations issued to you at the close of the inspection.

The significant observations are as follows:

1. Failure to identify, quarantine and destroy a unit collected from an unsuitable donor. For example, Unit [redacted] was collected from a donor previously deferred due to Hepatitis C (HCV) reactive results. This unit was subsequently collected, processed, shipped and transfused.

2. Failure to identify and defer unsuitable donors, in accordance with standard operating procedures. For example, donors previously deferred for HCV were improperly re-entered into the donor pool. Units [redacted], [redacted] and [redacted] were collected, processed, shipped and transfused.

3. Written procedures are not available for handling units collected from deferred donors at the fixed donor sites.

4. Written procedures are not available for the investigation and evaluation of post donation information to determine if a potential error or accident occurred in manufacturing. Also, concerning unit [redacted]; all pertinent information necessary for appropriate evaluation and follow-up was not documented for HIV-related post donation information.

5. Incomplete validation of equipment used in testing and transporting blood products. There is no assurance that blood that is temporarily stored in coolers at mobile and fixed donor sites, is maintained at required temperatures. In addition, written procedures for maintenance of blood in the coolers are lacking and/or inadequate.

6. Failure to maintain in donor adverse reaction records in accordance with written procedures.

7. Written procedures, including donor history forms, are inadequate for donor suitability regarding travel/emigration from malaria endemic areas, donors taking finasteride or Soriatane, and exposure to hepatitis or yellow jaundice.

8. Failure to prepare donors' venipuncture site in accordance with written procedures.

The above deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of federal regulations, with regard to blood collection, processing, testing and distribution. You should take prompt action to correct these deviations. Failure to implement corrections may result in regulatory action without further notice.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including supporting documentation and an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measure will be implemented. Your written response should be sent to the Food & Drug Administration, New Jersey District Office, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,

Douglas I. Ellsworth
District Director
New Jersey District